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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/975,982	11/21/1997	MARTINE CERUTTI	989.6442	1310

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SCHNADER HARRISON SEGAL & LEWIS, LLP
1600 MARKET STREET
SUITE 3600
PHILADELPHIA, PA 19103

EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/975,982	CERUTTI ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/27/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-10 and 12-15* is/are allowed.

6)☒ Claim(s) *11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Detailed Action

Receipt of the certified copy (and English translation) of the French application 94/01015 is acknowledged. Priority to the French application is granted.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 6,312,690 (hereafter the '690 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons of record in the previous Office Action (Mailed 4/23/03). It is noted that, upon reconsideration, claim 11 is rejected over only claim 16 of the '690 patent rather than claims 14-17 of the '690 patent; however, the grounds of rejection remain the same. Specifically, claim 16 of the '690 patent recites a recombinant monoclonal antibody wherein the polypeptide sequences of the light and heavy chains (these include the variable and constant regions) are human sequences while the instant claim recites any immunoglobulin

whose constant domain is coded by a human sequence. The claim in the '690 patent therefore anticipates the instant claim.

Applicants traverse this rejection by asserting that as a result of the claim for foreign priority based upon the French application 94/01015, the '690 patent is not available as prior art.

Applicant's arguments filed 10/27/03 have been fully considered but they are not persuasive. It is noted that obviousness type double patenting rejections are made against patents or applications independent of whether they qualify as prior art. Indeed, the need for filing of a Terminal Disclaimer is independent of whether a given application or patent, which forms the basis for the rejection, is filed prior to or after the filing date of the application under examination. The rationale underlying the prohibition against issuance of multiple patents claiming inventions not patentably distinct from each other is outlined in the following excerpt from the MPEP (804.02):

There are at least two reasons for insisting upon a terminal disclaimer to overcome a judicially created double patenting rejection in a continuing application subject to a 20-year term under 35 U.S.C. 154(a)(2). First, 35 U.S.C. 154(b) includes provisions for patent term extension based upon prosecution delays during the application process. Thus, 35 U.S.C. 154 does not ensure that any patent issuing on a continuing utility or plant application filed on or after June 8, 1995 will necessarily expire 20 years from the earliest filing date for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c). Second, 37 CFR 1.321(c)(3) requires that a terminal disclaimer filed to obviate a judicially created double patenting rejection include a provision that any patent granted on that application be enforceable only for and during the period that the patent is commonly owned with the application or patent which formed the basis for the rejection. This requirement serves to avoid the potential for harassment of an accused infringer by multiple parties with patents covering the same patentable invention (37 CFR 1.601(n)). See, e.g., In re Van Ornum, 686 F.2d 937, 944-48, 214 USPQ 761, 767-70 (CCPA 1982). Not insisting upon a terminal disclaimer to overcome a judicially created double patenting rejection in an application subject to a 20-year term under 35 U.S.C. 154(a)(2) would result in the potential for the problem that 37 CFR 1.321(c)(3) was promulgated to avoid.

Accordingly, a terminal disclaimer under 37 CFR 1.321 is required in an application to overcome a judicially created double patenting rejection, even if the application was filed on or after June 8, 1995 and claims the benefit under 35 U.S.C. 120, 121, or 365(c) of the filing date of the patent or application which forms the basis for the rejection.

It is also noted that for applications filed prior to June 8, 1995, a Terminal Disclaimer is required to prevent improper extension of patent term for a given invention.

It is noted that the Assignment data available to the Office indicates that the instant invention and the 6,312,690 patent **are not currently commonly owned**. If this is not correct, applicants need to inform the examiner of the current assignments of the instant application and the '690 patent.

Furthermore, it is noted that the inventive entity of the '690 patent is different from the inventive entity of the instant application. Since both the instant application and the '690 patent are claiming inventions not patentably distinct from each other, the inventorship of the common claimed subject matter is in question. This raises an issue under 35 USC 102(f) as to who invented the common subject matter. When an inquiry is made concerning inventorship under 35 USC 102(f) applicants are required to resolve the questions of inventorship of the common subject matter (See MPEP 2137, a portion of which is recited below):

Where there is a published article identifying the authorship (MPEP § 715.01(c)) or a patent identifying the inventorship (MPEP § 715.01(a)) that discloses subject matter being claimed in an application undergoing examination, the designation of authorship or inventorship does not raise a presumption of inventorship with respect to the subject matter disclosed in the article or with respect to the subject matter disclosed but not claimed in the patent so as to justify a rejection under 35 U.S.C. 102(f). However, it is incumbent upon the inventors named in the application, in reply to an

inquiry regarding the appropriate inventorship under subsection (f), or to rebut a rejection under 35 U.S.C. 102(a) or (e), to provide a satisfactory showing by way of affidavit under 37 CFR 1.132 that the inventorship of the application is correct in that the reference discloses subject matter invented by the applicant rather than derived from the author or patentee notwithstanding the authorship of the article or the inventorship of the patent. *In re Katz*, 687 F.2d 450, 455, 215 USPQ 14, 18 (CCPA 1982) (inquiry is appropriate to clarify any ambiguity created by an article regarding inventorship, and it is then incumbent upon the applicant to provide "a satisfactory showing that would lead to a reasonable conclusion that [applicant] is the...inventor" of the subject matter disclosed in the article and claimed in the application).

If the inventorship of the common subject matter is not resolved, interference proceedings may be initiated if Claim 11 is found to be allowable.

Any rejections not repeated in this Office Action are withdrawn.

Claims 1-10 and 12-15 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. After January 14, 2004, the examiner can be reached at (571) 272-0767. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DAVID GUZO
PRIMARY EXAMINER

David Guzo
January 7, 2004